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Comments of Consumers Union on U.S. Department of Agriculture Food Safety Inspection Service's Proposed Rule: Discontinuation of the Qualitative (30 mL) Campylobacter Analysis for Young Chickens Docket No. FSIS-2013-0037

Overview

Consumers Union (CU), the policy and advocacy arm of *Consumer Reports*, is pleased to submit these comments on the U.S. Department of Agriculture (USDA) Food Safety Inspection Service's (FSIS) decision to discontinue its qualitative test (30 mL) of young chicken products for *Campylobacter*.

We commend FSIS for recognizing that the high incidence of *Campylobacter* on poultry products poses an important food safety risk to U.S. consumers and for instituting testing to assess the levels of *Campylobacter* harbored by poultry processed in slaughter establishments and to develop pathogen reduction performance standards to indicate substandard process control at these processing facilities.

However, we are concerned that although past FSIS *Campylobacter* inspection included both quantitative (1 mL) direct-plating and qualitative (30 mL) enrichment tests, the qualitative testing has been suspended since June 2013. We feel that this suspension and the planned discontinuation of the qualitative test has and will put consumers at unnecessary risk by allowing *Campylobacter*-positive young chickens to go undetected during inspections.

While FSIS justifies the discontinuation of qualitative testing in large part based upon their finding of a lower classification sensitivity for that test compared with the quantitative test, we

feel that the assumptions underlying their statistical test were flawed and do not allow for an independent assessment of the added value contributed by the qualitative testing. In particular, defining the non-compliant data set for the sensitivity analysis based on the results of the quantitative test and then calculating the sensitivity of the quantitative and the qualitative tests using that data set would seem to favor the quantitative test.

Further, while quantitative testing may be sufficient to detect high levels of *Campylobacter*, lower levels that nevertheless present a threat to consumers may not be detected with this method alone and may require the use of qualitative testing. Additionally, reasons other than bacterial density may contribute to false-negative reporting by the quantitative test, for instance, the presence of pathogenic *C. coli* strains, which are not recovered as readily on the selective agar used for direct-plating, or the presence of *Campylobacter* strains that will reach high levels only after antibiotic-free enrichment allows them to recover from cell stress or injury. We feel that relying upon the quantitative test as the only measure to determine *Campylobacter* positivity in young chickens will give suboptimal detection rates and the false impression that process controls are adequate when they may not be.

Background

Campylobacter infection is one of the most common causes of foodborne illness in the U.S., and poultry consumption has been linked to infections and outbreaks (FDA Bad Bug Book 2012). Chickens frequently harbor *Campylobacter* as commensal organisms in their gastrointestinal tract, as many as 9 $\log_{10}$ CFU/g of feces, and horizontal transmission among members of a flock occurs readily prior to slaughter (Keener et al. 2004).

While some flocks are free of *Campylobacter* pre-harvest, transfer of bacteria from contaminated poultry can occur during processing, particularly at the point of defeathering (Keener et al. 2004). Although treatments and other processing aids can substantially reduce the bacterial load on contaminated chickens, as few as 500 *Campylobacter* cells are needed to cause an infection in humans, an amount that can be contained in a single drop of liquid from a mishandled or undercooked piece of retail chicken (CDC-NCEZID-DFWED Campylobacter General Information). Therefore, even retail poultry with low levels of *Campylobacter* can present a public health risk.

Since 1998, FSIS enacted Hazard Analysis and Critical Control Points (HACCP), which includes process control, microbial testing, pathogen reduction performance standards, and sanitation standard operating procedures. However, HACCP efforts to reduce contamination of meat and poultry with harmful bacteria and reduce the risk of foodborne illness did not include efforts to reduce *Campylobacter* levels on retail poultry until 2009, when FSIS initiated a program to select a performance standard for *Campylobacter* in poultry. FSIS conducted baseline studies to estimate prevalence and to establish methodology for sampling different types of poultry and detecting *Campylobacter* using both enrichments and selective agar. After baseline studies, FSIS instituted a performance standard for young chickens in 2011, requiring that no more than

10.4% of sample sets tested be positive for *Campylobacter* using the quantitative (1 mL) test method. The quantitative method is able to detect samples that are contaminated with high levels of bacteria, but the qualitative method (30 mL), which includes an enrichment step, is more likely to detect low levels of contamination. During this period, FSIS used the qualitative test results for internal analysis and they were not used to determine whether samples were considered positive for compliance (McKee, S. 2012). FSIS suspended use of the qualitative method as part of its *Campylobacter* inspection program in June 2013, and only recently announced the method's discontinuation, which it justified based on the interpretation of data collected from the 3rd quarter of 2011 through the 1st quarter of 2013 (FSIS Campylobacter Method Comparison Report). Although FSIS shows sensitivity and cost analysis to support their proposed discontinuation, it is our opinion that the methods for bacterial recovery and statistical analysis presented in their method comparison may have led to interpretations that undervalue the contribution of the qualitative (enrichment) test in the detection of *Campylobacter*.

Potential Negative Impact of Discontinuing the Qualitative Test

FSIS finds on average that the quantitative (1 mL) test will find a sample positive only when levels of *Campylobacter* on carcasses are 30 times higher than what can be detected using the qualitative (30 mL) test for evaluation of contamination (FSIS Campylobacter Method Comparison Report). And in the same FSIS report, some sample sets called compliant by the quantitative test, would have been deemed non-compliant if qualitative test results had been used to classify compliance for the same sets.

We are concerned that elimination of the qualitative test will yield artificially low numbers of "true" *Campylobacter*-positive sets, and that the misclassification of sample sets will result in a failure to detect substandard process controls. Because *Campylobacter* prevalence varies by flock and cross-contamination events (i.e., transfer of *Campylobacter* from flocks that test positive upon slaughter to flocks that test negative upon slaughter) occur during processing, the failure to detect substandard process controls may result in unwanted and undetected spread of *Campylobacter*. Further, it is possible that *Campylobacter* contamination during processing may occur at lower levels than would be detected by quantitative (1 mL) testing alone since at least 15 CFU/g is necessary to be considered positive by direct plating.

Thus, even as the number of young chickens becoming contaminated by substandard process controls increases--putting consumers at greater risk of encountering *Campylobacter* on their chicken--the number of recorded instances of non-compliance may not increase because the levels of *Campylobacter* may be lower than the limit of detection for the quantitative test. This is a particular worry because the infectious dose of *Campylobacter* is quite low, and that birds that fail to test positive by quantitative methods (but might test positive by qualitative methods) could still cause infections in consumers.

Qualitative Test's Enrichment Detects *Campylobacter* that Quantitative Test Misses

Campylobacter are fastidious bacteria that can be challenging to culture, as they are thermophilic, require specific atmospheric conditions, and often grow at different rates (Advisory Committee on the Microbiological Safety of Food, 2005). Thus, the combined use of direct plating and enrichment prior to plating may be required for optimal detection of *Campylobacter* species, which are not always recovered using just one of these methods (Gharst et al. 2006). In its baseline study, FSIS included the enrichment step "to supplement the direct plating for increased sensitivity of qualitative detection for low levels of potentially injured cells" (FSIS Method for Campylobacter Baseline Study). The rationale for this makes sense; enrichment delays antibiotic selection, so that *Campylobacter* cells subjected to stress or injury during the carcass rinse and transport to the laboratory have the opportunity to recover and be successfully cultured in order to give an accurate representation of postchill contamination.

Further, enrichment methods may be especially important if background contamination with other microbes results in their overgrowth relative to *Campylobacter*. In this case, the qualitative (30 mL) test would allow multiplication of low levels of bacteria that could later be detected in sufficient numbers on selective media.

Finally, the selective agar used for the quantitative (1 mL) test may not be suitable for all species of *Campylobacter*. Pathogenic *C. coli* does not grow well on Campy-Cefex agar, but is nonetheless an important cause of gastroenteritis and the methodology for assessing *Campylobacter* contamination should capture growth of this species as well as *C. jejuni* (Oyarzabal et al. 2005).

Overall, FSIS noted that a higher percentage (17% vs. 6%) of samples tested positive for *Campylobacter* by the qualitative test than the quantitative test during their 2011-2013 method comparison period (FSIS Campylobacter Method Comparison Report). Since ultimately the compliance with the HACCP performance standard is measured by presence or absence of *Campylobacter* in inspected sample sets, the surest way to assess presence or absence is using both test methods. We feel there is insufficient evidence to show that the quantitative test alone is adequate for determining presence of *Campylobacter* due to its limited ability to detect *Campylobacter* at all but the highest levels and its potential to underreport *C. coli*, which is a credible public health threat.

Critique of FSIS Sensitivity Comparisons

The FSIS reported negligible added benefit for the classification sensitivity of samples sets as non-compliant when the qualitative (30 mL) test was used in addition to the quantitative (1 mL) test, as measured sensitivity increased from 99.85% to 99.97%. Their measure of the quantitative test alone was 99.85%, but the lower classification sensitivity (79.33%) reported for the qualitative test may have been an artifact of bias introduced through the way in which the data were analyzed to determine classification sensitivity, and, as discussed below, this

measure may appear lower than its potential due to the use of culture methods that were suboptimal for enrichment-based recovery. The issue regarding their statistical analysis is especially concerning because the sensitivity results are presented as a crucial piece of evidence upon which FSIS based its decision to discontinue qualitative testing.

1) Sample Set Criterion and Determination of Non-compliance for Sensitivity Favored the Quantitative Test

The sample set criteria for the two types of testing methods was different: >8/51 for quantitative (1 mL) vs. >27/51 for qualitative (30 mL). Based on FSIS's own analysis, it appears that at least 8 of 248 sets had qualitative results at or exceeding the set criterion of >27/51 yet were classified as compliant by the quantitative >8/51 set criterion (FSIS Campylobacter Method Comparison Report). Misclassification of this sort resulting from interpretation of only the quantitative test presents both a risk to public health and in the FSIS's ability to adequately monitor for *Campylobacter*.

Moreover, FSIS noted in their discussion, "The 30 mL portion sample set criterion could be reduced to improve its classification sensitivity" (FSIS Campylobacter Method Comparison Report)**.** This is an important point. First, a reduction in the set criterion for the qualitative test would appear more sensitive in the comparison analysis. For instance, ~14 sets had more than 20 positive samples in qualitative testing but were below its >27/51 set criterion. Overall, not presenting a range of calculated sensitivities based on adjusting the sample set criterion for the qualitative test may have contributed to a potential undervaluing of the qualitative test's ability to identify *Campylobacter*-positive samples in the FSIS comparison, as well as an underestimation of its sensitivity in determining non-compliance based on set results. Third, the FSIS did not suggest reducing the sample set criterion for the quantitative test to <9 positive samples, but it is noteworthy that such an adjustment would allow the quantitative test to detect more non-compliant establishments.

Beyond the sample set criteria, the main issue at fault with the conclusions FSIS draws about the utility of the qualitative (30 mL) test is that their statistical test of classification sensitivity is conducted using the pool of non-compliant establishments determined by the current performance standard, which is based on the quantitative (1 mL) test. Use of this metric means that establishments were allocated to the non-compliant pool if >8/51 quantitative tests were positive, without regard for how they might have been classified using the qualitative test. Despite this imbalance, the sensitivity for both test methods (quantitative and qualitative) was determined from this non-compliant establishment pool. Therefore, the sensitivity of the quantitative test (i.e., the cumulative binomial probability having test results positive for >8/51) would seem to be heavily favored relative to the sensitivity of the qualitative test, whereas the qualitative test's probability of classifying non-compliance (i.e., >27/51 positives) was not intricately linked to the way the data pools were determined for the sensitivity analyses. The interconnectedness of the non-compliant establishment pool being defined by the quantitative test results can

be viewed as influencing the evaluation of how well that very test predicts those same establishments to be non-compliant. As FSIS's proposed discontinuation of the qualitative testing is largely based on their sensitivity analysis, it is concerning that the values they present do not give an assessment free from the confounding effects of the quantitative test's definition of non-compliance.

2) Rinsate Volume not Optimal for Enrichment Culture Conditions

A rinsate volume of 400 ml was used by FSIS to obtain samples from postchill carcasses. A concern raised by the National Advisory Committee on Microbiological Criteria for Foods during method development by FSIS prior to baseline studies indicated that the proposed volume of rinsate was larger than the optimal 100 ml recommended for qualitative detection:

> "...based on preliminary results from the ARS/FSIS Broiler Rinse Study, the higher volume of rinse used in the FSIS HACCP verification program (FSIS uses 400 ml BPW, ARS method calls for a 100 ml) may contribute to a lower observed Campylobacter spp. count for broiler rinses, as compared to what is being observed in the ARS project.
>
> FSIS should determine the specific volume and type of rinse to be used, taking into account any additional microbiological assays being performed as part of the baseline, and provide scientific justification for the volume chosen. Referencing statistically valid studies/documents comparing different rinse volumes should be included. Rinse solutions should be at 4°C before rinsing, and rinsate should be immediately placed on ice."
>
> (2005 NACMCF comment on FSIS Campylobacter method)

Thus, the rate of positive samples detected by the qualitative method may have been less than if the smaller volume of rinsate had been used, resulting in a lower observed sensitivity relative to the sensitivity observed using the quantitative method, which was not likely to be affected by rinsate volume.

3) Campy-Cefex Selective Agar not Optimal for use after Enrichment

At least one study that conducted a comparison of various selective agars for *Campylobacter* recovery after enrichment found that Campy-Cefex selective agar, the agar that FSIS uses in both its qualitative and quantitative tests, may not not be the best choice for qualitative testing due to background growth of non-*Campylobacter* species (Chon et al. 2012). Because plating on this media following enrichment may favor other competing microbial species, it is possible that FSIS observed a lower isolation rate and classification sensitivity for *Campylobacter* using the qualitative test than if that test had employed a different selective media that would suppress the growth of background flora on agar after the enrichment step.

Recommendations for Strengthening *Campylobacter* Detection

The qualitative (30 mL) test was initially proposed as a conditional test that would be conducted as a back up for samples testing negative by the quantitative (1 mL) method. However, in order to make a comparison between the two disparate methods in terms of their relative sensitivities and specificities, FSIS presents aggregate results using parallel interpretation where a positive by either method results in classification of the sample as positive; in reality, the HACCP performance standard (10.4%) is set based upon presence of *Campylobacter* in the quantitative test. Instead, we suggest using the qualitative test as originally proposed: interpret quantitative test results when they are positive, and interpret qualitative test results for samples that return negative results in the quantitative test. In this way, the *Campylobacter* performance standard could be assessed based on the true presence of contamination on the chicken, as assayed by a sensitive (quantitative) and a more forgiving (qualitative) method, rather than the present interpretation based on just bacteria that were able to survive the limitations of the growth conditions provided by direct plating in the quantitative method. In its report, FSIS recognizes that a performance standard based on both sample portions would allow for more non-compliant establishments to be detected, which in turn "might motivate more…establishments to improve their process control, thereby reducing exposure of consumers to contaminated poultry meat" (FSIS Campylobacter Method Comparison Report).

As mentioned in the recent FSIS directive, *Campylobacter* categories have not been set and are not published as they are for *Salmonella* (FSIS Directive 2013). We would encourage reporting of *Campylobacter* sample test results to increase transparency of the process controls' effectiveness in limiting contamination, and we would also call for consequences, including holding or recalling products, when establishments' test results do not meet performance standards.

Finally, we would suggest the FSIS pursue pre-harvest testing for *Campylobacter*, which countries such as Ireland have instituted. Pre-harvest identification of flocks that harbor high levels of *Campylobacter* allows interventions such as scheduled slaughter, which can limit the cross-contamination to flocks that arrive for slaughter free of *Campylobacter*-contamination.

Conclusion

Reliance on only the quantitative (1 mL) test for detection will target those carcasses with higher levels of *Campylobacter* when determining whether young chicken slaughter establishments are compliant with acceptable percentages of *Campylobacter*-positive carcasses. One concern of targeting only detection of higher levels is that slaughter establishments may implement process controls to merely reduce the levels of *Campylobacter* below the level detected by quantitative test but not eliminate lower-level "positives" that would have been detected by the qualitative (30 mL) test. A reactionary, chemical-based approach may be used to address a short-term performance issue while a more concerning systemic problem of contamination could still lurk; such methods may only affect the high levels but not effectively reduce the presence of (and

thus consumer exposure to) *Campylobacter* on chicken. Ultimately, low levels of contamination of retail chicken still pose a risk to consumers and if they are not detected, FSIS inspections will underestimate the actual annual incidence of *Campylobacter* and not assure that process controls are implemented to the fullest extent. In order to pursue accurate surveillance, regulation, and reduction of *Campylobacter* in young chickens processed in the U.S., FSIS should continue to assess *Campylobacter* using both qualitative and quantitative methods, as it is in the best interest of public health.

The change in performance standard for *Campylobacter* seems to be contingent on the FSIS conclusion that the qualitative (30 mL) is a less sensitive assay. However, this conclusion is drawn from FSIS's own statistical analysis of classification sensitivity for detecting non-compliance, which was calculated among establishments already deemed to be non-compliant based on quantitative (1 mL) results. Therefore, high sensitivity of the quantitative test was a foregone conclusion. In spite of that, FSIS data (i.e., Figure 2 in its Method Comparison document) show that the qualitative (30 mL) test identifies some establishments for which *Campylobacter* samples test >27/51 but were classified as compliant using the performance standard based on the quantitative test alone. We urge you not to allow for a performance standard that relies only on detecting high levels of *Campylobacter*, as this could give the public the erroneous impression that *Campylobacter* incidence has improved when it may not have. We believe you should set a strong performance standard and ensure that the testing we do today can be compared to previous results. A change in performance standard should reflect a true change in expected rates. Until then, we urge you to continue the qualitative test and allow its contribution to the performance standard. The FSIS data does not show that detection of the quantitative test alone is equivalent to the two tests together, nor is a negative result in quantitative test indicative of the microbiological "absence" of *Campylobacter*.

Our own tests have shown that the prevalence of *Campylobacter* on retail chickens can be as high as 62% (Consumer Reports 2010). **While we are very interested in truly lowering the levels of *Campylobacter* in chicken and having stronger performance standards, we do not believe that eliminating the qualitative test, which has the ability to detect lower levels of bacteria, is scientifically sound. We are concerned that a new performance standard of >8/51 using the quantitative assay would lead the public to believe that levels of *Campylobacter* on chicken have actually improved when that is not the case. In fact, FSIS has already shown that it would have deemed 8 plants compliant using the quantitative test than it otherwise would have using the qualitative test.** In order to be able to track progress on *Campylobacter* management practices, we also need to have comparable data of prevalence, and that would point toward keeping the qualitative test until we truly get better control of *Campylobacter* levels on poultry. We do appreciate the value of *Campylobacter* quantification and over time, if that test proves able to detect the lower levels we have previously achieved with the qualitative test and correctly identify non-compliant establishments, we recognize that eliminating the qualitative test would be possible. **We rely on FSIS to ensure that we are doing the most possible to address the presence of campylobacter in poultry and as such, urge you to *not drop the qualitative test***. Negative results in the quantitative test are not equivalent to *Campylobacter*-free conditions and the detection threshold

of the quantitative test requires up to 30-times greater levels of bacteria than qualitative assay. **We believe the best way to ensure accurate detection of *Campylobacter* and the safety of our food supply is maintain or meaningfully strengthen the performance standard against the continued use of the qualitative test.**

Respectfully submitted,

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